DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M32781

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER
VIA EXPRESS

JAN 25 1999

Mr. Enrique Salcedo Padilla
Supertex Industrial, S.A. De C.V.
Carretera A Bosques De San Isidro No. 1136
Zapopan, Jalisco, Mexico C.P. 45147

Dear Mr. Padilla:

During an inspection of your firm located in Zapopan, Jalisco, Mexico, on October 19-23, 1998, our investigator determined that your firm manufactures latex examination gloves. These gloves are devices as defined by Section 201(h) of the Federal, Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation, as specified in Title 21, Code of Federal Regulation (CFR), Part 820, as follows:

1. Failure to document validation activities and results, as required by 21 CFR 820.75(a). For example, there is no documentation available for review to show that the entire latex manufacturing process was validated at the initial start of the operation.

2. Failure to document revalidation activities and results, as required by 21 CFR 820.75(c). For example, there is no documentation available for review for revalidating the latex manufacturing process when a change to the process is made.

3. Failure to ensure that in-process product is controlled until the required inspection and tests or other verification activities have been completed, or necessary approvals are received, and are documented, as required by 21 CFR 820.80(c). For example, eighty-seven out of approximately [redacted] plastic boxes of gloves in the production area were labeled with tags that were missing lot numbers. [redacted] of the boxes were under quarantine, and [redacted] of the boxes contained gloves placed in the boxes after completion of processing. The boxes were stored next to one another.

4. Failure to establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality, as required by 21 CFR 820.70(e). For example:

   a. Employees were observed picking up gloves from the floor, which was dirty, in the area where gloves are removed from the molds and the glove washing area, and placing them back in the plastic boxes;

   b. Opened pails of paint and drums with water are stored next to the accepted raw material; and

   c. The floor area at the southwest corner of the building was covered with a film of [redacted]used on the gloves, which could possibly create dust when the [redacted] dryers are operating.

5. Failure to establish and maintain procedures for the control of storage areas and stock rooms for product to prevent mix-ups, damage, deterioration, contamination or other adverse effects pending use or distribution, and to ensure that no obsolete, rejected, or deteriorated product is used or distributed, as required by 21 CFR 820.150(a). For example:

   a. There is no method for distinguishing in-process products from finished products when they are stored together in a chain-link fenced area in the south central part of the building;

   b. The raw material warehouse appeared to be dirty and untidy, and is used to store raw material, machine and equipment parts and other items that should not be stored next to accepted raw material that is used in the latex manufacturing process;

   c. A vertical gap approximately 5 inches wide was observed between the two large metal doors at the shipping end of the building and could admit insects and dust, which could contaminate raw materials and finished devices.

6. Failure to identify by suitable means the acceptance status of product, to indicate the conformance or nonconformance of product with acceptance criteria, and failure to maintain the identification of acceptance status throughout manufacturing, packaging, and labeling of the product to ensure that only product which has passed the required acceptance activities is distributed or used, as required by 21 CFR 820.86. For example, accepted raw material are missing acceptance stickers.

7. Failure to establish and maintain requirements for the cleanliness and personnel practices of employees if contact between such personnel and product could reasonably be expected to have an adverse effect on product quality, as required by 21 CFR 820.70(d). For example, there is no hot water in the bathroom for hand washing, and one employee was observed not washing his hands.

In addition to the above Quality System Regulation deviations, the FDA Dallas District International Activities Branch in Laredo, Texas took samples of your gloves in August and September of 1998, and found the gloves to be out of compliance according to the FDA 1000 ml Water Leak Test. Additionally, a sample of your gloves collected by our Los Angeles District Office was also found to be out of compliance with our water leak test. As a result of these findings, your latex exam gloves were put on import alert on September 14, 1998.

We acknowledge receipt of your January 11, 1999, response to the form FDA 483; however, we could not perform an adequate review of it because all attachments are in Spanish. Please resubmit your response in English, and once it has been evaluated, we will communicate to you any concerns that we may have. In the meantime, please do not delay in responding to this Warning Letter within the time frame given below.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance system. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Given the serious nature of these violations of the Act, all latex examination gloves manufactured by Supertex Industrial S.A. De C.V. of Zapopan, Jalisco, Mexico may be detained upon entry into the United States (U.S.) until these violations are corrected.

In order to remove the devices from this detention, it will be necessary for you to provide a written response to the charges in this Warning Letter for our review. After we notify you that the response is adequate, it will be your responsibility to schedule an inspection of your facility. As soon as the inspection has taken place, and the implementation of your corrections have been verified, your products may resume entry into this country.

Please notify this office in writing within 15 days of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make correction to any underlying systems problems necessary to assure that similar violations will not recur. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter. If documentation is not in English, please provide an English translation to facilitate our review. Please address your response and any questions to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement II, General Hospital Devices Branch, HFZ-333, 2098 Gaither Road, Rockville, Maryland 20850, to the attention of Ms. Carolyn Niebauer.

Should you require any assistance in understanding the contents of this letter, do not hesitate to contact Ms. Diane Goldsberry at the letterhead address or at (301) 594-4618 or FAX (301) 594-4638.

Sincerely yours,

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health